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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/629,321

07/28/2003

David Delaney

SKEL-007

6585

24353

7590

12/14/2006

BOZICEVIC, FIELD & FRANCIS LLP
1900 UNIVERSITY AVENUE
SUITE 200
EAST PALO ALTO, CA 94303

EXAMINER

JONES, DAMERON LEVEST

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/629,321

Applicant(s)

DELANEY ET AL.

Examiner

D. L. Jones

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/28/06.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 and 25-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 and 25-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 9/28/06 wherein claim 24 is canceled and claim 30 is added.

Note: Claims 1-23 and 25-30 are pending.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

2. The Applicant's arguments and/or amendment filed 9/28/06 to the rejection of claims 1-23 and 25-29 made by the Examiner under 35 USC 103 have been fully considered and deemed non-persuasive for the reasons set forth below.

103 Rejection

The rejection of claims 1-23, 25-29, and newly added claim 30 under 35 USC 103(a) as being unpatentable over Wenz (WO 2004/050131) in view of Constantz et al (US Patent No. 6,334,891) and Constantz et al (US Patent No. 6,719,993) is MAINTAINED for reasons of record in the office action mailed 6/30/06 and those set forth below.

Applicant's arguments may be summarized as the instant invention is distinguished over the prior art of record because the prior art, unlike the instant invention, discloses that the contrast agent is eliminated/leaked out of the calcium phosphate compound.

Applicant's arguments have been considered. However, the arguments are not persuasive because both Applicant and the cited prior art are directed to a product, use of the product, and method of making the product (a cement) wherein the product comprises a setting fluid and dry reactants comprising a calcium source and a

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phosphate source. Applicant asserts that the primary references, Wenz discloses that the water-soluble contrast agent, the iodide compound is leaked out of and eliminated from the product. While Applicant's assessment of the prior art may be true, the claims do not set forth any conditions to ensure that the water-soluble contrast agent remain incorporated in the calcium phosphate compound. Thus, the claims as written do not require that the contrast agent remain permanently incorporated. As a result, whether the contrast agent of the prior art remains incorporated for 1 hour, 2 days, 4 years, etc. is unknown.

It is respectfully suggested that Applicant submit some type of evidence (i.e., a declaration) to the effect that the contrast agent of the prior art remains permanently incorporated into the calcium phosphate product and/or amend the claims such that the ratio of the setting fluid and the dry reactants result in a product wherein the contrast agent remains incorporated (this would be provided that Applicant has evidence (i.e., support of the instant disclosure) to such teachings). In other words, it is respectfully suggested that Applicant review the instant application and determine what, if any, limitations that could be incorporated into the claims to distinguish the claims over the cited prior art. Otherwise, it is the Examiner's position that both the prior art and the instant invention disclose overlapping inventions.

Note: It is duly noted that Applicant has added claim 30 which is directed to the contrast agent being present in an amount ranging from about 10 to about 35% by weight. However, Wenz, page 5, paragraph [0017], discloses that the amount of the radiopacity enhancing additive (i.e., contrast agent), depending on the type of the

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additive and the radiopacity enhancing effect on the hardened calcium containing phosphate cement, ranges between at least 0.5 percent to about 25 percent by weight. Thus, the range set forth in newly added claim 30 is encompassed by the prior art of record.

COMMENTS/NOTES

3. Applicant is respectfully requested to replace 'abut' with 'about' in claim 30, line 2.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

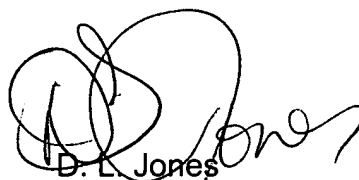
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



D. L. Jones
Primary Examiner
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December 11, 2006